REMARKS

Claims 1-4, 6.13, 15-19 and 21-23 were rejected.

Following receipt of the Office Action mailed on October 4, 2006, examiner Laura Hill sent a fax to applicant's attorneys, a copy of which is attached. The fax advised that the examiner was prepared to allow this case if applicant consented to the examiner amending the title, amending claims 1 and 7, and canceling claim 2, all as set forth in the fax.

Following the receipt of this fax, applicant's attorney (Marc E. Brown) and the examiner spoke over the phone. Applicant's attorney authorized the examiner to make all the changes requested in her fax, with one exception. Instead of amending claim 1 to specify types of fluid so as to avoid a double-patenting concern, applicant instead proposed to file a terminal disclaimer. The examiner said that this would be acceptable.

Thereafter, applicant filed a terminal disclaimer.

Unfortunately, applicant has not yet received the amendment that the examiner said she would enter and the accompanying notice of allowance. Applicant's attorney (Marc E. Brown) again phoned the examiner today, April 4, 2007. The examiner acknowledged receipt of applicant's terminal disclaimer and indicated that she was prepared to enter the amendments discussed above and to allow this case. Unfortunately, today is also the six month deadline to respond to the office action. Out of an abundance of caution, therefore, applicant's attorney advised that he would instead file the amendment to which applicant and the examiner had agreed, so as to place this case in condition for allowance.

Applicant has now made this amendment. It is therefore believed that this case is in condition for allowance. Early notice of the same as so initially requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the

filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

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FAX COVER SHEET

Please note this is not official Office action but is intended only to speed prosecution. Below is a proposed Examiner's amendment to issue the following cases: 11/420,702; 11/420,695; 10/775,666; 10/776,022; and 10/776,020.

Please respond to Examiner Hill directly ASAP for all cases except 10/775,666 which requires a response **no later than 6:00 pm EST on Thursday, March 1st.**

6 pages including this cover sheet

Thank you,
Examiner L. Hill
571-272-7137 (phone)
571-273-7137 (direct fax)

To: Marc Brown
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Fax: 310-277-4730
Please note this is not official Office action but is intended only to speed prosecution. Below is a proposed Examiner's amendment to issue the following cases: 11/420,702; 11/420,695; 10/775,666; 10/776,022; and 10/776,020.

Attny docket 64693-163
Case serial no. 11/420,702

Please **change the title** to: A method of Utilizing a Surgical Drain with Sensors for Monitoring Internal Tissue Condition.

1. A method of utilizing a surgical drain to monitor the condition of a tissue in a body, comprising:

a. fully implanting a surgical drain configured to be implanted within the body to rest against a surface of but not penetrating the tissue to be monitored and to drain fluid from the vicinity of the tissue, wherein the surgical drain includes a sensing element that is integrated with the surgical drain and configured to sense a physiological property of the tissue;

b. sensing, by the sensing element, energy indicative of the physiological property directly from the tissue;

c. receiving information corresponding to the sensed energy, wherein the information pertains to a physiological property of the tissue; and

d. monitoring the information received so as to evaluate the condition of the tissue over time; and determining a lack of contact between the surgical drain and the tissue.

Cancel claim 8.

--Note the "configured" language inserted is to avoid 101 rejections. Alternatively, note the word "adapted" could be exchanged with the word "configured" to avoid 101 rejection.

--Note the subject matter of claim 8 was incorporated into independent claim 1 to avoid provisional obvious double patenting rejection of claim 21 of case 10/776,020.

The art of record alone or in combination fails to disclose or fairly suggest a surgical drain system or method comprising a surgical drain to rest against the surface of the tissue and configured to not penetrate the tissue that has transmitting & draining elements in combination with a processor that determines a first color that is representative of detected spectral energy from a sensing element and a display configured to depict the color to assist a physician in determining the health of at least one tissue.

Benaron et al. (US 5,769,791) discloses surgical tool 30,210 with tip 40 passing through or around internal body tissue (column 10, lines 29-38) or alternatively resting on tissue 207 and not penetrating through ti (column 18, lines 14-15, figure 6) comprising first transmitting element 22, 241,242 provides a light control signal using optical fibers (column 9, lines 23-31, column 18, lines 15-18), first sensing element 24, 245, 246 that receives signals corresponding to the detected light (column 18, lines 20-21, figure 6),

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performs a color analysis and ascertains the desired spectral characteristics of the detected light, and provides the spectral data to the signal processor 26 (column 9, lines 32-36) which in turn provides the type of tissue to display system 28 (column 9, lines 38-42). However, Benaron doesn't disclose a surgical drain having a tube to transport drained fluid out of the body or sensor and transmitter embedded within tool.

Crowley (US 6,882,875) discloses an interventional device 10, 90 inserted into the body (column 3, lines 15-16) and positioned against tissue 92 (column 5, lines 1-2, figure 5A) comprising a first transmitter 20 on the inner surface of the body (column 3, lines 25-40, figure 1), a sensor or light source 16 or LEDs 38a, 38b for providing a signal (column 3, lines 45-52, column 4, lines 16-20), processor and display 14 (column 3, lines 19-24) but no surgical drain having a tube to transport drained fluid out of the body or sensor and transmitter embedded within tool or motivation to combine with surgical drains since all other surgical drains (e.g. Russo US 4,317,452) penetrate inside the tissue and don't have sensing or transmitting means.

Takezawa et al. (US 5,108,364) discloses catheter 1 that is *implanted into a body cavity* and thus penetrates the tissue (column 3, lines 55-65) having temperature sensor 10 that detects energy and embedded within the catheter (column 4, lines 9-15), processor and display (column 4, lines 9-10) and drainage holes 5 (column 3, lines 29-38, figure 1A), and a second sensor that can simultaneously measure temperature at a plurality of regions (column 4, lines 24-26). However, there is no transmitter or colors that are determined or depicted but rather temperature is monitored.

Bedingham (US 5,421,328) discloses an arterial catheter 53 with oxygen sensor 69, carbon dioxide sensor 71, and pH sensor 73 affixed to a distal end of transmitting element/optical fibers 75,77,79 on an inner surface of the catheter (column 7, lines 46-51, column 8, lines 2-4 and figure 2). Thus the catheter is implanted and penetrates the tissue.

Sullivan et al. (US 4,497,324) discloses a urinary , interperitonial, intercardial, respiratory or intervascular catheter penetrating the tissue (column 5, lines 7-11) having drainage lumen 20 (column 3, lines 31-39), temperature transducer/sensor 32 imbedded in the catheter wall to detect temperature and convert said temperature to an electrical signal (column 3, lines 60-63), and a transmitting element/electrical lead 34 imbedded in the cathteter wall (column 4, lines 19-20).

Yanda (US 4,413,633) discloses catheter tube 10 inserted into a urethra and thus penetrating the tissue that forms the urethra and connected to drainage tube 30 (column 2, lines 32-35 and lines 42-47), sensor 38 and transmitter on inner surface of the catheter (column 3, lines 18-39 and figure 2).

Pavoni et al. (US 5,906,584) discloses electrodes/sensors 5 on outer surface of catheter 3 but catheter is inserted within tissue, and a monitor/reading apparatus and a power supply/energy delivery transmitting element (column 4, line 36-column 5, line 8, figures 6-7). Also there is no drain disclosed.

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Frazee (WO 92/11803) discloses cardiopulmonary monitoring system 100 that transmits and receives optical signals to and from the interior of the penetrated blood vessel via fiber optic catheter 10, monitor/display, and processing (see abstract, etc).

Attny docket 64693-162
Case serial no. 11/420,695

Proposed Examiner's Amendment

Please **change the title** to: Implanted Surgical Drain with Drain Holes for Monitoring Internal Tissue Condition.

Claims submitted 2/15/07 stand allowable based on the same rational used with 11/420,702 described above.

Attny docket: 64693-029
Case serial no. 10/775,666

Please **change the title** to: Implanted Surgical Drain with Sensing and Transmitting Elements for Monitoring Internal Tissue Condition.

Claims submitted 2/14/07 stand allowable based on the same rational used with 11/420,702 described above.

A response to approve this title change in this case is **due by 6:00 pm EST on Thursday, March 1st due to time constraints faced by Examiner.

Attny docket: 64693-0101
Case serial no. 10/776,022

Please **change the title** to: Implanted Surgical Drain with Multiple Sensing Elements for Monitoring Internal Tissue Condition

1. A surgical drain for sensing a physiological property of at least one tissue and draining fluid from a body comprising:

a) an elongated conduit configured to be implanted in a patient's body and rest against a first tissue and a second tissue within the body to drain fluid from the patient's body, wherein the elongated conduit comprises a drain portion having openings spaced along substantially the length of the drain portion~~;~~, wherein the surgical drain is not configured to penetrate either the first or second tissues;

b) a first sensing system....

c) a second sensing system...

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25. A surgical drain for sensing a physiological property of at least one tissue and draining fluid from a body comprising:

a) an elongated conduit configured to be implanted in a patient's body in proximity to an organ at a first location and to a tissue that is not part of the organ at a second location that is different from the first location, the elongate conduit comprises a drain portion having openings spaced along substantially its length and configured to drain fluid from the patient's body in the vicinity of the organ and the tissue~~;~~, wherein the surgical drain is not configured to penetrate the tissue;

b) a first sensing system....

c) a second sensing system...

--Note parts b) and c) in both independent claims 1 and 25 remain their language as submitted 1/22/07.

See the rationale above with respect to 11/420,702 for description of prior art

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Attny docket: 64693-102
Case serial no. 10/776,020

Please change the title to: Implanted Surgical Drain with Multiple Sensing Elements for Monitoring Fluid Lumen

1. An implantable surgical drain for draining fluid from and sensing a condition of a surgical wound within a patient's body comprising:

an elongated conduit having a drain lumen configured to be implanted within the surgical wound and to rest against ~~tissue within the surgical wound~~ but not penetrate the tissue and a plurality of drain holes spaced along substantially the length of the drain lumen that are configured to drain fluid from the surgical wound, wherein the elongated conduit is configured to drain blood, puss, bile or intestinal contents; and

at least one sensing element affixed to the elongated conduit and configured to sense a biochemical property of drained fluid within the drain lumen.

--Incorporate the subject matter from claim 2 into claim 1 to avoid obvious double patenting rejection with claim 1 of 11/420,695 and with claim 68 of 10/775,666.

7. An implantable surgical drain for draining fluid from and sensing a condition of a surgical drain within a patient's body comprising:

an elongated conduit having a drain lumen configured to be implanted within the surgical wound and to rest against ~~tissue within the surgical wound~~ but not penetrate the tissue and a plurality of drain holes spaced along substantially the length of the drain lumen that are configured to drain fluid from the surgical wound, the elongated conduit including a first position and a second position located within the drain lumen;

a first transmitting element placed proximate to the first position, configured to deliver energy into the drain lumen; and

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a first sensing element placed proximate to the second position, configured to receive the delivered energy after it is modulated by a biochemical property of at least one substance within the lumen.

--Cancel claim 2.

See the rationale above with respect to 11/420,702 for description of prior art

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Please respond to Examiner Hill directly ASAP for all cases except 10/775,666 which requires a response **no later than 6:00 pm EST on Thursday, March 1st.**

Note there are no outstanding obvious double patenting issues between these cases as amended.

Thank you,

Examiner Laura Hill
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